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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/484,928	06/07/1995	GARY K. MICHELSON	P-12509	5055

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EXAMINER

REIP, DAVID OWEN

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/484,928

Applicant(s)

MICHELSON, GARY K.

Examiner

David O. Reip

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002 and 07 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 173-199, 201-228, 231-233, 235-252, 255-272, 275-277, 279-293 and 295-300 is/are allowed.
- 6) ☒ Claim(s) 301-310, 313-320 and 323-335 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 23 October 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 173-199,201-228,231-233,235-252,255-272,275-277,279-293,295-310,313-320 and 323-335.

DETAILED ACTION

Specification

The amendment filed 10/23/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the paragraph bridging pages 9 and 10, referring to Fig. 3A, the last sentence of added text, "The insertion end of the implant may also be larger than the trailing end where so desired," constitutes new matter. There is no original disclosure, including consideration of both textual disclosure and drawing figures, of an embodiment of the invention having an insertion end larger than the trailing end.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 301 is objected to because of the following informalities: In line 9, "at least a portion an interior" is missing the word "of," and should be changed to read --at least a portion of an interior--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 301-304 and 306-308 are rejected under 35 U.S.C. 102(b) as anticipated by McIntyre (U.S. Pat. No. 4,950,296). Figs. 1-4 and the whole of the disclosure of McIntyre show two embodiments of non-threaded spinal fusion implants having all the limitations as recited in claims 301-304 and 306-308, including: "mesh-like" material (both embodiments 10 and 26 show implants comprising cortical and cancellous bone material, such material being inherently "mesh-like"); a plurality of openings 18 or 20 creating hollow interiors; surface "roughenings" (bone material is inherent "rough"); at least one planar surface (see Figs 3-4); and fusion promoting material (bone).

Claims 305 and 330-333 are rejected under 35 U.S.C. 102(b) as being anticipated by Rostoker et al (U.S. Pat. No. 3,906,550). Figs. 1 and 5 show embodiments of non-threaded, cylindrical bone implants made from metal mesh. Implant embodiment 18 (see Fig. 1) and implant embodiment 42 (see Fig. 5) each present a size capable of being inserted between two adjacent vertebrae and are of sufficient rigidity so as to be capable of supporting the vertebrae (see co. 3, line 45 through col. 4, line 31). With respect to claim 330, the limitation "being formed of a cancellous material" is met in the implant of Rostoker et al, since the definition of cancellous is "having a course net-like or spongy structure." The metal mesh of Rostoker et al can certainly be said to be a course net-like structure.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 309-310, 314-320, and 324-329 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy et al in view of Brantigan (4,878,915) and Pavlov et al (U.S. Pat. No. 5,906,616). Godefroy et al discloses the implant claimed including the recited tapered configuration with ramped bone engaging projection portions 13/14/16 (see Fig. 3) and in combination with fusion promoting material (see col. 3, line 60 through col. 4, line 19 for disclosure of the implant being filled with a spongy bone graft to promote fusion), but does not set forth the various claimed surface details. However, the numerous surface configurations suggested by Brantigan provide ample evidence to support a conclusion of obviousness in providing the Godefroy et al implant with these various surface configurations for the purpose of enhancing bone ingrowth and fusion. In Brantigan, see the knurling in Fig. 6, the ratchetings in Fig. 8, the pits (corresponding to "porous", "wells", and openings as recited) in Fig. 7, and the surface roughening in Figs. 10 and 11. Additionally, while it is acknowledged that the ramped bone engaging portions 13/14/16 of Godefroy are oriented opposite to that of the instant invention, i.e. with the "ramp" surfaces facing toward the larger end of the implant, it would have been obvious to one of ordinary skill in the art at the time the invention was made to design a modified embodiment of the Godefroy et al implant having the reverse orientation of the ramped bone engaging portions, i.e. with the "ramp" surfaces facing toward the smaller

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end of the implant, in order to facilitate insertion of the implant smaller end first. Note the teaching of Brantigan in Fig. 8 showing an implant having ramped bone engaging portions which facilitate insertion and resist retraction of the implant. Further, note the teachings of Pavlov et al. In Godefroy et al, it is the insertion end that is larger than the trailing end rather than the converse as discussed above. However, Pavlov, et al. gives ample evidence that both options are equally well known. Compare Figs. 7-9 with Figs. 21-23 of Pavlov et al. It would have been readily obvious to employ the Godefroy et al implant in both an insertion mode where the leading end is smaller, and an insertion mode where the trailing end is smaller, depending on the particular portion of the spine in which the implant is used and whether a conventional anterior or posterior approach is used, in order to obtain the benefits of the Godefroy implant regardless of the method of implanting it.

Claims 313 and 323 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy et al in view of Ducheyne. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example). It would have been obvious to one of ordinary skill in this art to employ such mesh-like material in the implant of Godefroy et al in order to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claims 334 and 335 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rostoker et al in view of Lemons (U.S. Pat. No. 5,273,964). Lemons teaches the

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use of BMP with porous implants in order to promote bone growth through the implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, in view of Lemons, to include the use of BMP or any of the recited fusion promoting substances in order to enhance bone ingrowth as explicitly suggested by Lemons.

Allowable Subject Matter

Claims 173-199, 201-228, 231-233, 235-252, 255-272, 275-277, 279-293, and 295-300 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip at (703) 308-3383. The examiner can normally be reached Mon-Thu and every other Fri from 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano, can be reached at (703) 308-2496. The fax number for this Unit is (703) 308-2708 (unofficial) or (703) 872-9302 (official). The examiner can also receive direct-to-computer faxes at 703-746-3310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858.

A handwritten signature in black ink, appearing to read "David O. Reip", with a stylized flourish at the end.

David O. Reip
Primary Examiner
February 13, 2003